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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,881	01/16/2004	Oscar S. Gluck	3954P2748	8468

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,881	GLUCK ET AL.	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of the species disclosed in claim 4, i.e., the species wherein the PAD inhibitor has a side chain including a benzamide group to the left and an ester to the right of a peptide bond, in the reply filed on January 20, 2006 is acknowledged.

Claims 1-6 are presented for examination as they read upon the elected species.

Claim Objections

Claim 4 recites the limitation "has a side chain including a benzamide group to the left and an ester group to the right of a peptide bond" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).

Nature of the invention. The claims are drawn to methods of using a PAD (peptidylarginine deiminase) inhibitor to treat a host for rheumatoid arthritis.

State of the prior art. At the time the invention was made, successful implementation of therapeutic methods related to citrunillation stoppage and/or experimental evidence that PAD inhibitors would actually work as therapeutics for rheumatoid arthritis are not disclosed by those skilled in the art. This is reflected by two subsequently published reviews. Sebagg et al. teach that, as of 2004, "Numerous questions about the pathophysiological significance of the autoimmune response to deiminated proteins in rheumatoid arthritis remain to be answered..." (p. 493, abstract). The authors go on to state, "a new animal model of rheumatoid arthritis based on an autoimmune response to deiminated fibrin should prove to be very useful not only in future pathophysiological researches but also in the assessment and validation of new therapeutic approaches (See, e.g., page 499, column 1, lines 1-5).

Breadth of the claims. The claims are extremely broad, encompassing treatment of any and all rheumatoid arthritis instances in any animal.

Working examples. No working example is disclosed in the specification.

Guidance in the specification. The specification provides little guidance regarding practice of the claimed methods. The specification refers generally to gene delivery systems in use at the time the invention was made, which are of questionable efficacy as discussed above. There is no specific guidance regarding actually using

PAD inhibition to treat/prevent rheumatoid arthritis in a host. The specification does not disclose the effect, if any, of administering PAD inhibitors to any hosts.

Predictability of the art. The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). In the instant application, Applicants have not disclosed how the method works, e.g., once the autoantibodies have formed, will it be therapeutically useful to reduce the amount of citrullination of proteins?, i.e., the disease process has started, and the body would be expected to keep producing those antibodies. Would it be necessary to completely shut down the enzyme to prevent the antibodies from attacking? There is no way to predict what would be the consequences of this and, e.g., if it is even possible to shut down the whole enzymatic pathway with administration of such inhibitors.

Amount of experimentation necessary. Besides the general expectation that it will require years of further research to understand the significance of the autoimmune response to deiminated proteins (Sebagg et al, page 493, abstract), it would require extensive research to understand the fundamental biology of the system (such as a new animal model, e.g., Sebagg et al. page 499, column 1, lines 1-5). It is not know what function PAD inhibition would have in the overall treatment of rheumatoid arthritis. Applicants have identified an interesting enzymatic pathway, which might play a role in some diseases, but essentially all of the work required to ultimately develop a treatment method has been left for others.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rendered vague and indefinite because it is unclear whether the peptide bond referred to in such claim is written from N to C or from C to N, and it is unclear with respect to what the phrase "side chain" is referred to. Also, the limitation "has a side chain including a benzamide group to the left and an ester group to the right of a peptide bond" in line 1 has insufficient antecedent basis (no frame of reference for "left" or "right".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pritzker et al. (Biochimica et Biophysica Acta, 1998) in view Brahn (US 5,583,153).

Pritzker et al. teach a PAD (peptidylarginine deiminase) inhibitor, taxol (see, e.g., abstract, Figure 1A, page 155, column 2).

Pritzker et al. do not teach a method of treating rheumatoid arthritis with a PAD inhibitor.

Brahn teaches a method of using taxol in the treatment of rheumatoid arthritis. (e.g., abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention to use taxol, which intrinsically is a PAD inhibitor as taught by Pritzker, in a method of treating rheumatoid arthritis as taught by Brahn.

Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MMCG 03/06

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